Chronicles of Food Protection

www.vdacs.virginia.gov/fdsafety December 2007

Food Safety

Ready Business

Ready Business outlines common sense measures business owners and managers can take to properly prepare for emergency situations. It provides practical steps and easy-to-use templates to help you plan for your company's future. These recommendations reflect the Emergency Preparedness and Business Continuity Standard (NFPA 1600) developed by the National Fire Protection Association and endorsed by the American National Standards Institute and the Department of Homeland Security. It also provides useful links to resources providing more detailed business continuity and disaster preparedness information.

How quickly your company can get back to business after a terrorist attack, a hurricane, a fire, or a flood often depends on emergency planning done today. While the Department of Homeland Security is working hard to prevent terrorist attacks, the lessons of the 1993 World Trade Center bombing, the 1995 Oklahoma City bombing and the September 11, 2001 terrorist attacks demonstrate the importance of being prepared.

When you also consider that the number of declared major disasters nearly doubled in the 1990s compared to the previous decade, preparedness becomes an even more critical issue. Though each situation is unique, any business can be better prepared if it plans carefully, puts emergency procedures in place, and conducts routine mock training exercises for all types of emergencies.

America's businesses form the backbone of the nation's economy. Small businesses alone account for more than 99% of all companies with employees. These businesses employ 50% of all private sector workers and provide nearly 45% of the nation's payroll. If businesses are READY to survive and recover, the nation and our economy are more secure. A commitment to planning today will help support employees, customers, the community, the local economy and even the country. It also protects your business investment and gives your company a better chance for survival.

Both business continuity and **crisis management** can be complex issues depending on the particular industry, size and scope of your business. However, putting a plan in motion will improve the likelihood that your company will survive and recover. Companies that already have their emergency plans in place can continue to help create a more robust, sustainable community by mentoring businesses in their own supply chain and others needing advice.

We invite you to review the Ready Business link on our Web site: **www.vdacs.virginia.gov/foodsafetybioterroism.shtml** or you can visit Ready Business directly at: **www.ready.gov/business/index.html**.

Preparing makes good business sense. Get ready now!

FDA Recalls

The recall of a defective or possibly harmful consumer product is often highly publicized in newspapers and on news broadcasts. This is especially true when a recall involves foods, drugs, cosmetics, medical devices and other products regulated by the Food and Drug Administration (FDA). Despite this publicity, FDA's role in recall activities is often misunderstood not only by consumers, but also by the news media, and occasionally even by the regulated industry.

The following headlines, which appeared in two major daily newspapers, are good examples of that misunderstanding: "FDA Orders Peanut Butter Recall," and "FDA Orders 6,500 Cases of Red-Dyed Mints Recalled."

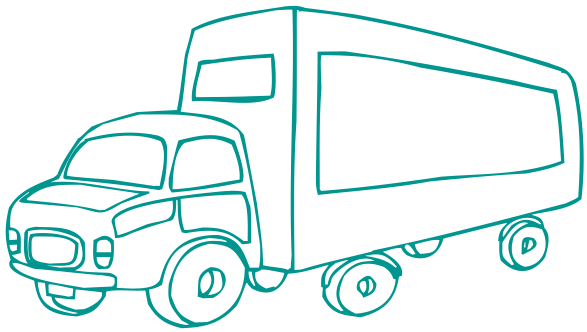
The headlines are misleading in indicating that the Agency can "order" these recalls. The Federal Food, Drug, and Cosmetic Act, (the law) does not generally authorize FDA to "order" a manufacturer to recall a food, cosmetic or supplement. The agency may formally request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request. It is only when human tissue products, a medical device or infant formula pose a risk to human health that the law specifically authorizes FDA to prescribe a recall and to rule on the scope and extent of the same*.

The manufacturers or distributors of the product carry out most recalls of products regulated by FDA voluntarily. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and requests a recall. Usually, the company complies.

If the firm does not recall the product, then FDA can seek legal action under the Food, Drug and Cosmetic Act. These include seizure of available product, and/or injunction of the firm, as well as a court request for recall of the product.

This cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of FDA, as well as industry, to get unsafe and defective products out of consumer hands as soon as possible.

FDA guidelines for companies to follow when recalling defective products under the Agency's jurisdiction are published in Title 21 of the Code of Federal Regulations, Part 7. These guidelines make clear that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, companies are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls, and to undertake recalls when asked to do so by the Agency.



The guidelines also call on manufacturers and distributors to develop contingency plans for product recalls that can be put into effect if and when needed. FDA's role under the guidelines is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned and investigates why the product was defective.

Generally, FDA accepts reports and other necessary recall information submitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. However, FDA maintains the prerogative for investigational visits and other in-person communications where the agency considers it appropriate.

The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

- **Class I** recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinum toxin, food with undeclared allergens, a label mix-up on a life saving drug or a defective artificial heart valve.

- **Class II** recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.

- **Class III** recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink; and lack of English labeling in a retail food.

FDA develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that each defective product has been recalled or reconditioned. In contrast, for a Class III recall, the Agency may decide that it only needs to spot check to make sure the product is off the market.

Even though the firm recalling the product may issue a press release, FDA seeks publicity about a recall only when it believes the public needs to be alerted about a serious hazard. For example, if a canned food product, purchased by a consumer at a retail store, were found by FDA to contain botulinum toxin, an effort would be made to retrieve all the cans in circulation, including those in the hands of consumers. As part of this effort, the Agency also could issue a public warning via the news media to alert as many consumers as possible to the potential hazard.

FDA also issues general information about new recalls it is monitoring through FDA Enforcement Reports found at: **www.fda.gov/opacom/enforce.html** This a weekly publication available on FDA's internet page at: **www.fda.gov/**. You can also visit their Recalls, Market Withdrawals and Safety Alerts link at: **www.fda.gov/opacom/7alerts.html** to get up-to-date recall information. For additional information on recalls, contact the FDA District Office nearest you: **www.fda.gov/ora/inspect_ref/iom/iomoradir.html**

In addition to FDA recalls, USDA, the Virginia Department of Agriculture and Consumer Services and other states participate in and initiate recalls when and where appropriate.

*Sec. 412, and Sec. 518, Food Drug and Cosmetic Act; Sec. 351 Public Health Service Act.

Food Security

FDA ALERT Program

Have you ever thought about what you eat, where it comes from, or even how it is grown? In an effort to raise awareness among government and industry, FDA has introduced the ALERT Program.The acronym, ALERT stands for Assure, Look, Employees, Reports, and Threats. The main focus of the program is to further open channels of communication between the government and industry. By keeping industry and government aware of issues relating to food defense and preparedness, information and communication can flow freely. The ALERT acronym is made up of five key elements that will easily assist a business with decreasing any associated risk of contamination or tampering.

Following is an overview of FDA's ALERT program:

How do you **ASSURE** that the supplies and ingredients you use are from safe and secure sources?

- **Know your suppliers.**
  Always obtain your food and materials from a reputable supplier. Make sure they are licensed, permitted, or inspected before purchasing anything.
- **Encourage your suppliers to practice food defense measures.**
  Ensure that the personnel with whom you do regular business (suppliers, transporters, etc.) are practicing food defense measures to ensure that the supply you receive is safe and wholesome.
- **Request locked and/or sealed vehicles/ containers/railcars.**
  Inquire about transportation methods and check upon arrival. If seals are used during transport, obtain that seal number for your records and verify the number and that the seal is intact upon arrival.
- **Supervise off-loading of incoming foods and materials.**
  Know about your investment from start to finish. Each shipment is your hard earned money at work. To ensure that your investment is protected, be there! Supervise and thoroughly inspect each shipment when they arrive at your business.

How do you **LOOK** after the security of the products and ingredients in your facility?

- **Implement a system for handling products.**
  Develop a universal system that your business can

use for receiving, handling or returning, food and other materials. A systems style approach will ensure that the important components of your internal food security system are addressed.

- **Track materials.**
  Make sure that you keep an accurate written record of all foods and materials.
- **Store product labels in a secure location and destroy outdated or discarded product labels.**
- **Limit access and inspect facilities.**
  This cannot be stressed enough - protect your investment. Only allow current employees into designated employee work areas. Regularly inspect the facilities (trucks, storage warehouses, etc.) where your product is located. At each of these locations, inspect the refrigeration units, electricity and various other controls.
- **Keep track of finished products.**
  Make sure that the establishments that you do business with are practicing food security.

What do you know about your **EMPLOYEES** and people coming in and out of your facility?

- **Conduct background checks on staff.**
  For each and every person hired at your operation, whether seasonal, part-time, full-time or contract, invest in a reputable agency that can provide the necessary data needed to assist you with the hiring process.
- **Know who belongs in your facility.**
  Only current employees should be at your facility. Know when and where they should be located once on the premises.
- **Establish an identification system for employees.**
  Many businesses use uniforms as a way of identifying employees. Name tags with business logos and photo or electronic badges are also very popular.
- **Limit access by staff.**
  It is a good idea to base employee access to the business facility by job function.
- **Prevent customer's access to critical areas of your facility.**

Could you provide **REPORTS** about the security of your products while under your control?

- **Periodically evaluate the effectiveness of your security management system.**
  Conduct mock exercises of potential real life situations. This will enable you to identify problems within your security system and revise them if necessary.
- **Perform random food defense inspections.**
  Check all aspects of your business on a regular basis. Assemble a team of individuals that can perform such tests or hire a third party.
- **Establishment and Maintenance of Records.**
  Keep an accurate record of sources and recipients of food.
- **Evaluate lessons learned.**
  Learn from past situations involving tampering or other criminal acts.

What do you do and who do you notify if you have a **THREAT** or issue at your facility, including suspicious behavior?

- **Hold any product that you believe may have been affected.**
- **Contact the Food and Drug Administration 1-888-463-6332 or the Virginia Department of Agriculture and Consumer Services' Food Safety and Security Program at (804) 786-3520**

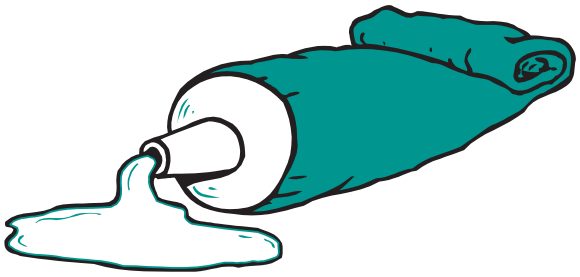
VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

For additional information, please visit FDA's Web site at the following: **www.cfsan.fda.gov/~dms/alert.html**

In an effort to spread this message, FDA and VDACS can provide the food industry with "ALERT" related free brochures, wallet-sized cards and posters while supplies last. A web-based training module has also been developed to raise awareness of the issues related to food defense. The training module will provide industry with the information they need to begin thinking about ways to prevent intentional food contamination within their facilities. View the ALERT training module and obtain more information on ALERT or other food defense-related issues at **www.cfsan.fda.gov/fooddefense**.

FDA and VDACS urge anyone to report suspected criminal acts involving food. FDA can be contacted using their 24 hour emergency number (301) 443-1240 or by calling a local district office.

For your convenience, a list of district offices can be found at the following website: **www.fda.gov/ora/inspect_ref/iom/iomoradir.html**. You may also contact VDACS at (804) 786-3520 or your local 911 centers in the event of a foodemergency.



Counterfeit Toothpaste

During June 2007, The Colgate–Palmolive Company and FDA warned consumers that counterfeit toothpaste falsely packaged as "Colgate" had been found in several dollar-type discount stores in five states: New York, New Jersey, Pennsylvania, Maryland and Virginia. There were indications that this product did not contain fluoride and may have contained a substance called Diethylene Glycol. The Company stated that it does not use, nor has ever used, Diethylene Glycol as an ingredient in Colgate toothpaste anywhere in the world.

The Colgate-Palmolive Company and federal, state and local government agencies aggressively pursued a resolution to the situation. After alerting FDA about the issue, Colgate contacted all its accounts handling Colgate toothpaste in the U.S. to ensure that they did not have any counterfeit product. Any accounts that did identify suspected counterfeit product were asked to remove it from sale.

The Company picked up suspected counterfeit product mostly located in small, independent dollar-type discount stores in the states where it had reportedly been distributed. Results of these efforts were provided to the U.S. Food and Drug Administration.

FDA spokesman Doug Arbesfeld was quoted in various new reports in reference to the Diethylene Glycol found by the FDA in some counterfeit samples, "It's a low health risk but the bottom line is, it doesn't belong in toothpaste." Analysis performed by Colgate Research and Development on counterfeit samples received came to the same conclusion regarding the low level of health risk.

To help the public identify the counterfeit toothpaste, the Company and FDA clarified the distinguishing characteristics. It came labeled as a 5 ounce or 100 ml tube, a size not made or sold by Colgate in the United States. Consumers could also identify the counterfeit product by the words on the package, "Manufactured in South Africa" as well as several misspelled words on the product carton including: "isclinically", "SOUTH AFRLCA", and "South African Dental Assoxiation". Colgate does not import toothpaste into the U.S. from South Africa.

Building on Colgate's long standing relationship with the American Dental Association and American Dental Hygienists Association, the Company provided information about the counterfeit product to over 50,000 dental professionals to assist them in answering patient questions.

Colgate representatives on its consumer information line (1-800-468-6502) also extended their hours of operation, added operations over the weekend and took other steps to answer consumer questions about counterfeit product. They also arranged for callers to provide them with any suspected counterfeit products and information about the purchase location.

In a statement made in June, Colgate Chairman and Chief Executive Officer Reuben Mark said, "We are all highly committed to reliability, quality and superior product performance. We will spare no effort to help consumers avoid counterfeits and support regulators in their efforts to remove these products from the marketplace."

If you suspect that you may have this counterfeit toothpaste in your business or home, call Colgate's toll-free number at 1-800-468-6502.

Reminder of Resources Available to You

It may have been a while since you visited the VDACS Food Security Web site (**www.vdacs.virginia.gov/food-safety/bioterrorism.shtml**). Therefore, we would like to take this opportunity to remind you of the resources that are available to you at this site.

It contains contact information for local police, a toll-free number for the State Police Domestic Terrorism Hotline and emergency contact numbers for the U.S. Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service Technical Service Center.

There is a link for information on the Certification of Foreign Workers and a link to Food Security Questions and Answers which includes information on how to report suspicious behavior and suggestions on how to conduct employee background checks.

Additionally, there are links to Virginia's Food Security Guide and FDA Guidance Documents for Processors and Transporters, Retailers, the Dairy Industry, and Importers. Your Food Safety Specialist can provide you with hard copy booklets of many of these guidance documents if you are interested in using them for food security training in your establishments.

References

Center for Food Safety and Applied Nutrition. (2007) ALERT: The Basics. FDA: Food Defense and Terrorism Program. Retrieved February 6, 2007 from **www.cfsan.fda.gov/~dms/alert.html**

Food and Drug Administration. (June 2002) FDA Recall Policies. Retrieved April 2, 2007 from **www.cfsan.fda.gov/~lrd/recall2.html**.

Food and Drug Administration. (2006) Restaurant X 123 Main Street, Phoenix, Arizona: Food Safety Manual. Vol. 1. Retrieved February 7, 2007 from **www.cfsan.fda.gov/~retrsk4/MaricopaCountyFoodSafetyManual.pdf**.

Food and Drug Administration. (2007) Update: Counterfeit Toothpaste Falsely Labeled as "Colgate". Retrieved June 18, 2007 from **www.fda.gov/oc/po/firmrecalls/colgateupd06_07.html**.

Minnesota Department of Agriculture, Dairy and Food Inspection Division. (2007) Handwashing. Retrieved February 6, 2007 **www.mda.state.mn.us/food/business/factsheets/handwash.htm**.

U.S. Department of Homeland Security. (2007) Ready Business. Retrieved May 19, 2007 **www.ready.gov/business/index.html**.

CHRONICLES OF FOOD PROTECTION

is published by the Virginia Department of Agriculture and Consumer Services' Division of Animal and Food Industry Service

Food Safety and Security Program
P.O. Box 1163, Richmond, VA 23218
Phone: 804/786-3520

Todd P. Haymore
Commissioner

Dr. Richard Wilkes, Director
Division of Animal and
Food Industry Services

Food Safety and Security Program
foodprotection@vdacs.virginia

Virginia Department of Agriculture and Consumer Services, www.vdacs.virginia.gov

NON-PROFIT
ORG
U.S. POSTAGE
PAID
RICHMOND, VA
PERMIT #1216